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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/664,711	09/17/2003	Budimir Drakulic	RECOM-64412	4390

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EXAMINER

LEE, YUN HAENG NMN

ART UNIT	PAPER NUMBER
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3766

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/664,711	DRAKULIC, BUDIMIR	
	Examiner	Art Unit	
	Yun H. Lee	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 December 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-54 and 78-89 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-54 and 78-89 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

1. Claims 1, 4, 16, 40-44, 49 and 53 are objected to because of the following informalities: In claim 1 line 7, the limitation "the characteristics" lacks proper antecedent basis. In claim 4 line 3, the limitation "the individual ones of the rows" lacks proper antecedent basis. In claim 16 line 3, the limitation "the member" lacks proper antecedent basis. In claim 40, the second to last paragraph ends with a comma even though it is not the end of the claim. In claim 41 line 5, the word "is" appears to be placed incorrectly. In claim 42 line 2, the limitation "the first electrode" lacks proper antecedent basis. In claim 42 line 4, the word "row" appears to be misspelled as "low". In claim 42 lines 6-7 and 8-9, the limitation "the third and fourth positions" lacks proper antecedent basis. In claim 43 last line, the limitation "the first electrodes" lacks proper antecedent basis. In claim 44 line 14, the word "of" appears to be misspelled as "pf". In claim 49 line 7, the word "at" is repeated. Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-6 and 32-39 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a vest constructed to be worn by a patient of small, medium or large size, does not reasonably provide enablement for a vest

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constructed to be worn by a patient regardless of the patient's size. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Examiner does not understand how a single vest could be constructed such that it could be worn by any person of any size ranging from a newborn infant to an individual with gigantism.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 42 and 43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Examiner does not understand the language of the paragraph beginning with "transfer" and suggests that Applicant rewrites the claim language in proper English grammar and idiom.

Claim Rejections - 35 USC § 101

6. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. Claims 5, 6, 12, 13 and 16 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 5 and 6 positively recite a part of the human body. Claims 12 and 13 positively recite a human being

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(patient). See Commissioner Donald J. Quigg's notice published at 1077 OG 24 (April 21, 1987). Claim 16 depends from rejected claim 12.

8. Claims 23, 24, 28-30 and 48 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible asserted utility or a well established utility.

Examiner finds Applicant's claim of an amplifier that produces signals independent of any noise that may result from the ambulatory nature of the patient to be incredible.

Claims 23, 24, 28-30 and 48 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 1-13, 16, 19-22, 32-39, 40, 41, 44, 45-47, 49-54 and 78-89 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greene (US. Pat. No. 3,525,330). Regarding claim 1, Greene discloses in a combination for providing signals at different positions in a patient,

a vest (10) constructed to be worn by the patient,
a plurality of electrodes (col. 1 lines 22-23) and
a plurality of positions (19) in the vest for receiving the electrodes, individual positions in the plurality of positions being disposed to receive the electrodes for signals indicating characteristics of the patient's heart when the patient has a small, medium or large size, the positions of the electrodes for the patient of small, medium and large size being individual (col. 1 lines 56-58) relative to the positions of the electrodes for patient of the other ones of the small, medium and large sizes.

Examiner took Official Notice in the previous Office Action that it is extremely old and well known to use amplifiers when dealing with biological signals in order to reduce noise, buffer signals, and provide a gain or amplitude increase. Lacking adequate traversal, this feature is now taken to be admitted prior art. Some examples of this well-known feature can be found in Lasch et al. (US Pat. No. 3,554,188), Sipple (US Pat. No. 3,565,060) and Day (US Pat. No. 3,611,174) just to list a few. Thus, it would have been obvious to one of ordinary skill in the art to use amplifiers responsive to the signals on the electrodes at the individual positions in the vest of Greene for providing signals indicating the characteristics of the patient's heart at the different positions for the patient when the patient has a small, medium or large size.

Regarding claim 2, Applicant admits in the present specification (page 10 lines 4-5) that the V₁-V₆ positions are well known in the prior art. Thus, it would have been obvious to one of ordinary skill in the art to position the electrodes of Greene at the positions V₁-V₆.

Regarding claim 3, Greene further discloses that the electrodes are disposed on the vest in rows and columns (col. 2 lines 36-43). Each of the electrodes in the vest will inherently be disposed in the vest in individual ones of the columns relative to the other electrodes in the vest when the patient has an individual one of the small, medium and large sizes if the electrodes are positioned to measure V_1 - V_6 positions since, by definition, these positions do not overlap vertically.

Regarding claim 4, Greene further discloses that the positions in the vest are disposed in rows and columns (19). Each of the amplifiers, as discussed above, will inherently provide indications of the heart in individual ones of the rows at an individual one of the columns when the patient has a small, medium or large size if the electrodes which provide the signals indicating the characteristics of the patient's heart at the different positions for the patient when the patient has a small, medium or large size are positioned to measure V_1 - V_6 positions.

Regarding claim 5, it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

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Regarding claims 6-13, 19-22, 40, 41 and 44, the limitations are met by the above discussion.

Regarding claim 16, the limitations are met by the above discussion. A common well-known amplifier, as discussed above, will reduce noise, buffer signals, and/or provide a gain or amplitude increase while substantially preserving the characteristics of the signals.

Regarding claims 32-39, the various claimed electrode configurations are simply in accordance with the V_1 - V_6 positions which is old and well known as discussed above. Thus, the limitations are met by the above discussion.

Regarding claim 45, Examiner takes further Official Notice that it is old and well known to include a low-pass filter in an amplifier used for ECG signals to eliminate noise and other signal contaminants. One example of such an amplifier can be found in Taylor et al. (US Pat. No. 6,304,773). Thus, it would have been obvious to one of ordinary skill in the art at the time of invention to include a low-pass filter in the amplifier discussed above to eliminate noise and other signal contaminants, substantially eliminating noise in the signals, regardless of the size of the patient during ambulatory movements of the patient.

Regarding claim 46, the terms “relatively common problems” and “relatively rare problems” are extremely broad in scope. Examiner takes the position that electrodes disposed in various positions are capable of providing signals indicative of “relatively common problems” as well as “relatively rare problems”. Greene discloses various positions for the electrodes, including the front of the patient (such as in the V₁-V₆ positions) and the back of the patient (col. 1 lines 35-37).

Regarding claims 47, 49-54 and 78-89, the limitations are met by the above discussion.

11. Claims 14, 15, 17, 18, 25-28 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greene (US Pat. No. 3,525,330) in view of the above discussion and further in view of Heilman et al. (US Pat. No. 5,078,134). Greene in view of the above discussion meets all the limitations of claims 14, 15, 17, 18, 25-28 and 31 except for an inflatable member for inflating the vest/electrodes. Heilman et al. discloses an inflator (322) for inflating a vest/electrodes against the patient's body to reduce the impedance at the electrode/skin interface (col. 12 lines 20-21). Thus, it would have been obvious to one of ordinary skill in the art at the time of invention to include an inflator in the vest/electrodes of Greene for inflating the vest/electrodes against the patient's body to reduce the impedance at the electrode/skin interface.

Response to Arguments

12. Applicant's arguments filed 12/18/2006 have been fully considered but they are not persuasive. Applicant argues that the references cited by Examiner do not disclose a vest in which the electrodes V₁-V₆ are disposed in individual positions in the vest when the patient has an individual one small, medium and large sizes. Examiner clearly noted that the V₁-V₆ positions for ECG electrodes are old and well known in the art. Also, Examiner did not reject the related claims as being anticipated by Greene, as would have been the case if Greene had in fact disclosed the identical positions, but rather rejected the claims as being unpatentable due to obviousness. Examiner further notes that Examiner already had considered separately whether the prior art discloses each individual element recited in each claim. If Examiner had found each individual element recited in each claim in one single reference, then Examiner would have obviously made an anticipation rejection under 35 U.S.C. 102. However, since Greene disclosed all elements of the claimed invention except for a few obvious features, Examiner rejected the claims under 35 U.S.C. 103 as being unpatentable due to obviousness.

Conclusion

13. Examiner noticed numerous errors within the claims as can be seen in the above claim objections. It is strongly suggested that Applicant carefully reviews every minor detail of the whole application to eliminate any errors that may hinder the prosecution and delay a potential allowance.

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

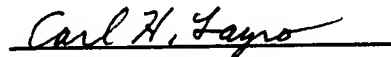
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yun H. Lee whose telephone number is (571) 272-2847. The examiner can normally be reached on M-Th 10-8.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl H. Layno can be reached on (571) 272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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